DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAY 2 2 2007

Re: Lunesta
Docket No.: 2005E-0255

The Honorable Jon Dudas
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This letter concerns the application for patent term extension for U.S. Patent No. 6,444,673, filed by Sepracor, Inc., under 35 U.S.C. § 156 et seq, and our May 15, 2007, letter determining the regulatory review period for Lunesta (eszopiclone), the human drug product claimed by the patent.

After our letter was issued, we realized that the determination of the regulatory review period for Lunesta was not routine and is affected by issues raised in a pending citizen petition. Consequently, we are withdrawing the May 15, 2007, letter determining the regulatory review period for Lunesta until we have completed our response to the citizen petition. We will respond to your request to determine the applicable regulatory review period as soon as possible after resolving the issues raised in the citizen petition.

We apologize for any inconvenience this may cause. Please let us know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Philip E. Hansen
Heslin Rothenberg Farley & Mesiti, P.C.
5 Columbia Circle
Albany, NY 12203-5160